

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

9

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/624,885 07/24/00 EDGE

A DNI-029

000959
LAHIVE & COCKFIELD
28 STATE STREET
BOSTON MA 02109

HM12/0927

EXAMINER

DECLoux, A

ART UNIT	PAPER NUMBER
----------	--------------

1644

DATE MAILED:

09/27/01

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/624,885

Applicant(s)

Albert Edge

Examiner

DeCloux, Amy

Art Unit

1644

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-42 are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

Detailed Action

1. A restriction is required under 35 USC 121 between one of the following groups:

I. Claims 1-19, drawn to a transplantable composition comprising isolated skeletal myoblast cells and isolated fibroblast cells, classified in Class 424, subclass 93.1,

II. Claims 1 and 20-27, drawn to a transplantable composition comprising isolated skeletal myoblast cells and isolated fibroblast cells, wherein an antigen on the surface of a cell is modified, masked or eliminated, classified in Class 424, subclass 93.21,

III. Claims 28-30, drawn to a method for preparing a transplantable composition comprising skeletal myoblast cells and isolated fibroblast cells, classified in Class 424, subclass 325,

IV. Claims 31-38, and 42 drawn to a method for treating a condition in a subject characterized by damage to cardiac tissue comprising administration of a transplantable composition comprising isolated skeletal myoblast cells and isolated fibroblast cells, classified in Class 424, subclass 93.7,

V. Claims 39-41, drawn to a method for promoting a cardiac cell phenotype in a skeletal myoblast comprising recombinantly expressing a cardiac cell gene product in the myoblast so that the cardiac cell phenotype is promoted, classified in Class 424, subclass 69.1,

Note: Each group will be examined only to the extent of the elected invention.

The inventions are distinct, each from the other because:

2. Groups III-V are unique methods. They differ with respect to their respective endpoints and process steps to achieve different goals. Therefore, they are patentably distinct each from the other

3. Groups I and II are different products. The products of Groups I and II differ with respect to their cell surface antigens; said an antigen of the latter group is modified, masked or eliminated, thereby conferring a distinct structure and function from that of Group I. Therefore Groups I and II are patentably distinct.

4. Group I and Group III are related as product and process of use, as are Group I and Group IV. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product, a transplantable composition comprising isolated skeletal

myoblast cells and isolated fibroblast cells, as claimed, can be used as an immunogen in a method of producing monoclonal antibodies, as well as in a method for preparing a transplantable composition comprising skeletal myoblast cells and isolated fibroblast cells, as encompassed by Group III, or in a method for treating a condition in a subject characterized by damage to cardiac tissue comprising administration of a transplantable composition comprising isolated skeletal myoblast cells and isolated fibroblast cells, as encompassed by Group IV.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because a search in the non-patent literature of any of these distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers (**other than elections**) should be faxed to Technology Center 1600 via the PTO Fax Center located In Crystal Mall 1. The faxing of such papers must conform with the notice published In the Official Gazette, 1096 OG

Serial No. 09/624,885
Art Unit 1644

-4-

30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner
Group 1640, Technology Center 1600
September 27, 2001



PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER

9/28/01